K030636

Section 10

510(k) Summary

CliniSurg Vascular Products

5454 Amesbury Dr. #2107
Dallas, TX 75206

CliniSurg Vascular Products
Premarket Notification 510(k) Summary
for the
C-Port Family of Implanted Vascular Access Devices

Part I
General Information

1.	**Submitter name:**	CliniSurg Vascular Products, LLC.
2.	**FDA Establishment Number:**	(number to be determined)
3.	**Address:**	5454 Amesbury Dr. #2107 Dallas, TX 75206
4.	**Phone:**	214-691-5935 (cell) 214-549-9208
5.	**Fax:**	Not available at this filing
6.	**Contact person:**	Donald F. Hults
7.	**Date prepared:**	February 14, 2003

8. **Device trade or proprietary name:**

   C-Port (family of Vascular Access Devices)

9. **Device common name or usual name:**

   Implantable Infusion Ports

10. **Device classification name:**

    Port and catheter, implanted, subcutaneous, intravascular (85-LJT)

11. Device classification:

The device is a Class II Device

12. Substantial equivalency:

Claimed against the following device(s):

- Titan Port or Vortex Port, from Norfolk Medical Products, now Horizon Medical Products since November 1998 (#K830000 – 1983).

13. Type of medical device:

The CliniSurg family of Vascular Access devices is a group of subcutaneously implantable ports with a catheter either pre-attached or attachable for application by physicians in indicated therapies.

14. Description of Device:

CAUTION: The device is to be used by or on the order of a physician.

The device has a port that is a titanium chamber with a silicone membrane designed for repeated needle insertion. The port comes in various sizes to enable use with larger adults or smaller pediatric patients or the more emaciated adult patient. A higher or lower profile device is chosen by patient evaluation. The port is connected to a catheter that is long enough to insert into the vena cava for positioning to enable fluid infusion into larger vessels. The catheter is fixed to the port with a hub either during a procedure to implant the device or it comes pre-assembled (physician choice for use). The catheter has a series of radiopaque marks to enable depth determination when the catheter is inserted into the vena cava. A kit is provided to aid in catheter placement, insertion, and port implantation. Items such as syringes, vein introducers, trocars, guide wires, sheaths, fixation hubs, Huber needles, and infusion sets may be part of a total kit.

15. Indications for use statement and product function:

The C-Port family of Vascular Access Devices will be used as a subcutaneously implanted device where repeated access to the vascular system is the therapy of choice for delivery of medications, fluids, nutritional solutions, and blood products or withdrawal of blood.

The C-Port family of ports and catheters provides a simple method for delivery of volumes of medications and fluids via a chamber leading to a catheter and opening into a large vessel in the body. The catheter is inserted into a large vessel and terminated in the superior vena cava. The port is implanted subcutaneously in the soft tissue near the clavicle on the patient's right upper chest wall. Medications or fluids can then be provided as necessary.

16. Contraindications or cautions for use:

A complete listing of the possible complications in the implantation and use of the C-Port family of ports is listed in the USER'S MANUAL which is supplied with the product. Possible complications in the use of the C-Port include, but are not limited to, infection, erosion, extrusion of the device, hematomas, clot formation, thrombosis, catheter fragmentation, and embolization, and occlusion. Improper placement of the catheter in the body has been shown to cause the catheter to be severed from a "pinching" effect by the clavicle and the first rib. **In the placement of the catheter into the vein and on into the superior vena cava, caution should be exercised to be sure that the catheter does not pass between the clavicle and the first rib.**

17. Methods (ways) of application:

The method of application is to prepare and insert the catheter into the vein (by "cut down" method or "percutaneous" method) and on into the vena cava. Then the proximal end of the catheter is tunneled subcutaneously to an area of cut down where the port is to be placed beneath the skin and secured to the fascial layers of tissue. The catheter is joined to the port (in attachable models) and the port is secured to the tissue. All wounds are then closed normally.

Intravenous fluids and / or nutritional fluids may then be administered by needle puncture of the septum in the port or periodic blood samples may be acquired if appropriate flushing techniques are followed (instructions for this are found in the USER'S MANUAL).

18. Special precautions for disposal of the device or emptied packages (container):

The sharps used in the procedure should be disposed of according to institution policy. Any remaining parts or empty packages do not require special handling when disposing.

19. Information on sterilization method(s):

a) For sterile products:

All C-Port family products that are manufactured by CliniSurg Vascular Products are sterilized by ethylene oxide gas. Sterilization details for validation, verification, bioburden, etc. can be found in the section on Risk Assessment (7.0) and Sterilization (8.0) in the CliniSurg Vascular Products 510(k).

b) For non-sterile products:

Not applicable. The C-Port family of products (ports and catheter kits) are packaged sterile. Any recognized open or damaged packaging should be noted, instructions in the User's Manual followed, and the product returned for evaluation and potential repackaging and re-sterilization or disposal.

20. Validity period:

As long as the package/product is unopened and undamaged the product is valid. The materials that make up the components of the C-Port family of products do not deteriorate over time.

21. Special precautions for handling and transportation:

Keep the product dry and do not open the package.

22. Description of package:

A C-Port product (port and catheter) is a basic cut-down set and is packaged in a plastic tray with:

1) 1-Huber Point Needle
2) 1-Huber Needle Infusion Set
3) 1-Vein pick (retracting device)
4) 1-Tunneling Trocar
5) 1-Blunt Needle

The plastic tray is heat sealed in a polyethylene/nylon Tyvek header bag (pouch) and sterilized. If requested, a percutaneous introducer kit is packaged with the C-Port product. This Port/Introducer Set is listed with its own catalog numbers and must be ordered as such. The percutaneous introducer kit contains:

1) 1-Sheath
2) 1-Dilator
3) 1-Guide Wire
4) 1-Syringe
5) 1-Needle

In addition, the C-Port is packaged with a User's Manual and Patient Implant stickers.

Each kit is packaged in an external fiberboard box. Each box is labeled appropriately to match the item inside the box.

23. Labeling:

Each product is labeled on its plastic container with a stick-on label containing the following information:

Company Name, Location, Contact Number
Product Name by Brand Name and Common Name
Model No.
Size of catheter
Lot Number registration
Units/package indicator
Restricted Device: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician
Sterile in unopened undamaged package
For single use only
Package contains information as noted in item 22 above

24. Instructions:

Detailed instructions for use and care of the C-Port are in the USER'S MANUAL. A simple listing of implant instructions is noted here:

1) Before implanting inspect the port. Do not use if holes, cracks, or surface contaminants are visible.
2) Flush all air from the port prior to placement using the 20ga. Huber point needle and syringe with heparinized saline.
3) The selected site for the reservoir body should be over a bony structure and in a location both convenient and comfortable for the patient.
4) Place the catheter into the vein using the "cut-down" technique or by using a percutaneous introducer.
5) Place the tip of the catheter in an area of high blood flow when placing it in the venous system. Fluoroscopy is recommended to verfiy proper placement of the catheter tip in the superior vena cava.
6) Take care not to serrate the catheter tip or occlude it during the catheter placement process. Leave sufficient slack upon placement so patient movement does not stress the catheter.
7) Position the pocket for the reservoir so that the suture line is not directly over the port. Do not place the port too deep or too shallow. A depth of approximately 5mm under the skin surface is recommended as the optimal placement depth.
8) Cut the catheter to the proper length and moisten all components with saline.
9) Slide the compression boot over the catheter.
10) Slide the catheter over the barbed outlet tube of the reservoir.
11) Slide the compression boot forward until the catheter and the outlet tube are completely covered.
12) Test by gently tugging on the catheter.
13) Secure the port to the underlying fascia with at least three non-absorbable sutures.
14) After suturing has been satisfactorily completed, flush the incision with an appropriate antibiotic to ensure a sterile pocket.
15) Before closure, check patency and flow through the C-Port by x-ray, fluoroscopy, or by an imaging technique of choice.
16) After each use, always leave the C-Port filled with a heparinized saline solution in a concentration recommended by your institution.

Part II

Detailed product characteristics

1. Structure (elements) of medical device material:

Component	Material
C-Port Base Plate (Body)	Titanium
C-Port Septum Retainer	Titanium
Port Septum	Silicone
Catheter	Silicone Rubber or Polyurethane
Connector Pin	Titanium
Catheter Boot	Silicone Rubber

All the materials in these components have been used in the market in predicate devices and other medical devices for an extended period of time. These materials do not present any new or modified mechanical or chemical specifications and are substantially equivalent to devices currently cleared for marketing in the United States.

If product is used with another medical material, present the name and safety conditions for their use:

The CliniSurg Vascular Products C-Port line of drug delivery depots should be accessed with a Huber point needle. It should be used according to standard hospital protocol for needle use.

2. Testing of components

All the components of the C-Port have been tested and meet the required specifications or items called for in the Guidance documents on Implanted ports, Long-term catheters, Sterility, and Biocompatibility. Types of testing that have been documented are as follows:

a) Catheter to Port connection test
b) Septum puncture test
c) Port leak test
d) Fluid dynamics test
e) Biological evaluation (toxicity)
f) Catheter body tensile strength
g) Catheter elongation strength

3. Kit certification

The C-Port is supplied with a kit for convenience in implanting by the surgeon and the institution. The items supplied in the kit for introducing the catheter to the venous system and for assisting in placement of the port are standard products commonly used in the marketplace for many applications. No new materials or product configurations have been introduced.

Part III

Risk Assessment

The C-Port is an implantable device requiring surgery for implantation. The risks associated with surgery in general are well documented and understood. There are no risks involved with the implantation of this device over the general risks associated with any surgical procedure.

Possible complications are presented in the literature that pertain to this class of devices. Possible notations are: infection, device erosion, hematoma, necrosis, device extrusion, clot formation, catheter fragmentation, embolization, catheter occlusion, A-V fistula, cardiac arrhythmia, cardiac puncture, cardiac tamponade, drug extravasation, fibrin sheath, endocarditis, implant reactions, migration of the port/catheter, perforation or laceration of the vessels, thoracic duct injury, thromboembolism, thrombosis, and superior vena cava syndrome. Improper placement of the catheter with the body has been shown to cause the catheter to be severed due to a "pinching" effect by the clavicle and the first rib. This device presents no known additional risks to the patient that are not well documented and for which there is already a prescribed therapy.

This device is similar to other devices currently on the market for which there is an abundance of medical information.

All of the materials used in this product are purchased to specifications that specify their use in a medical device and pose no additional or unknown risk to the patient.

All these materials have been successfully used in other Vascular Access products and present no unusual or unacceptable risks to the patient.

Part IV

Information on clinical studies performed

No clinical studies were performed as part of this 510(K) process as the product is identical to products currently cleared for marketing and can be applied for under the substantial equivalence claim.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 2003

Mr. Donald F. Hults
Manager
CliniSurg Vascular Products, LLC
5454 Amesbury Drive, # 2107
Dallas, Texas 75206

Re: K030636
Trade/Device Name: C-Port
Regulation Number: 880.5965
Regulation Name: Subcutaneous, Intravascular, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: May 19, 2003
Received: May 20, 2003

Dear Mr. Hults:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

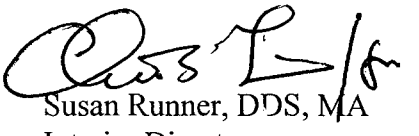
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: C-Port (family of Implanted Vascular Access Devices)
Port and catheter, Implanted, Subcutaneous, Intravascular – LJT

Indications for Use:

The C-Port family of products will be used as a subcutaneously implanted device where repeated access to the vascular system is the therapy of choice for delivery of medications, fluids, nutritional solutions and blood products or withdrawal of blood.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Patricia Cusenza

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030636